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TITLE: Preclinical Evaluation of a Decision Support Medical Monitoring System for Early Detection of Potential Hemodynamic Decompensation During Blood Loss in Humans

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This is a preclinical evaluation of non-invasive medical monitoring devices to predict blood loss and hemorrhage in humans. The goal is to develop technologies that can enhance decision support and resuscitation algorithms to treat combat casualties. In the last 12 months we have initiated the protocol and begun to compare simulated hemorrhage with lower body negative pressure (LBNP) with real blood loss of ~1 L. Two subjects have been studied to date and we are finding a remarkably tight correlation between LBNP levels of -15, -30, and -45mmHg with blood loss of 333 ml, 666 ml, and 1 L total. Notably, the changes in central venous pressure evoked by LBNP are similar to those evoked by real blood loss. Additionally, we are performing coagulation studies and also making detailed measurements of arterial pressure and heart rate. This primary data will be subject to further analysis including machine learning approaches designed to enhance the decision support algorithms developed by the U.S. Army Institute of Surgical Research. It should also be noted that the original project schedule has been delayed as a result of significant delays in the IRB process for review and approval of the experimental protocol.

15. SUBJECT TERMS
  Blood loss; decision support; resuscitation

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Introduction

This report details results from the first year of this study entitled "Preclinical Evaluation of a Decision Support Medical Monitoring System for Early Detection of Potential Hemodynamic Decompensation During Blood Loss in Humans." This technology was developed based on simulated hemorrhage generated using lower body negative pressure (LBNP). The purpose of this experiment is to compare results obtained using LBNP with real hemorrhage. We report on two subjects studied thus far. Subject recruitment was delayed due to significant time delays associated with re-review of protocol modifications by the DOD IRB.

Body

As noted above, we have conducted two complete studies comparing 1 L of blood loss in total to LBNP. Briefly, subjects are instrumented to measure arterial pressure (brachial artery catheter) and central venous pressure via a peripherally inserted central catheter. They are also subject to a host of non-invasive monitors that may ultimately complement the Army algorithm. Subjects are then subjected to lower body negative pressure at -15, -30, and -45 mmHg for 5 min each. During this time period continuous non-invasive monitoring measurements are made as well as recordings of directly measured arterial pressure and central venous pressure. Additionally, blood is drawn at selected time points to measure various markers of coagulation.

Key Research Accomplishments

Our accomplishments thus far include implementation of the protocol, successful approval and re-approval by Mayo and DOD IRBs, and successful completion of the first two studies.

Reportable Outcomes

We have raw data sets on two subjects. Figure 1 shows the CVP changes associated with LBNP and blood loss. Figure 2 shows selected TEG analysis. It is our plan to continue accrual and to perform a rigorous interim analysis after 6-8 studies have been conducted. This interim analysis will be performed in collaboration with our colleagues at the U.S. Army Institute of Surgical Research in San Antonio, TX.

Figure 1. Central venous pressure is nearly identical at each level of LBNP and blood loss.
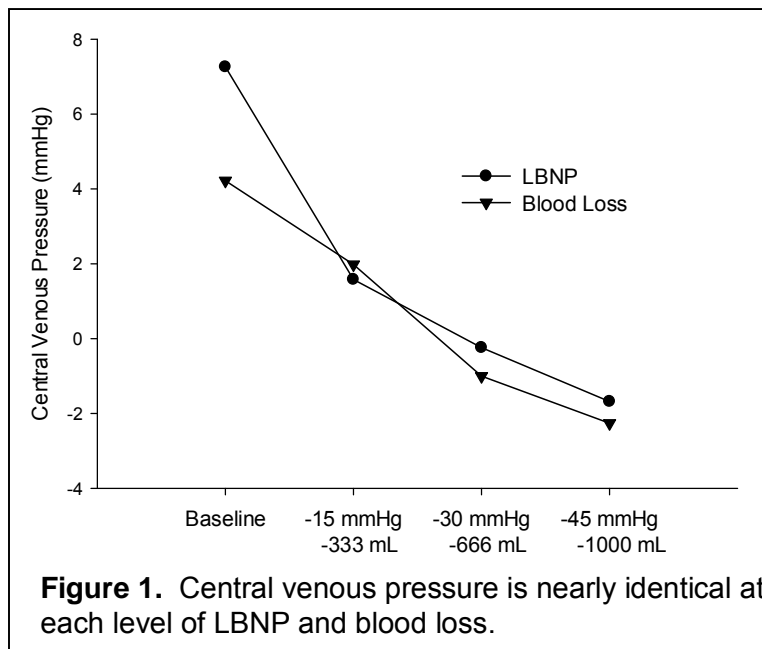
Conclusion

After delays associated with the IRB process, study progress has been strong, recruitment is moving at pace, and we anticipate accruing 1-3 subjects per month going forward. The data obtained thus far also tends to confirm the idea that LBNP is a highly useful surrogate for real blood loss in human studies.

References

N/A

Appendices

N/A

Figure 2. Time to fibrin formation (R) obtained by TEG is similar at both time points of LBNP and blood loss.